

Support for Amendment

Independent claims 1 and 21 are amended to characterize the freeze agent as glycerol. This amendment is supported by claims 11 and 22, and by the specification at, for example, page 7, lines 16-21.

Claims 11 and 22 are cancelled.

No new matter is introduced by this amendment, and entry thereof is requested. Upon entry, claims 1, 2, 4, 5, 9, 14, 21, 24-26, 28-31, and 33 are active in this application.

REMARKS

The outstanding Office Action acknowledges the withdrawal of the rejection based on U.S. Patent 6,368,786 to Saint-Ramon et al. Furthermore, the outstanding Office Action withdraws the rejection under 35 U.S.C. § 102(b) over European Patent No. EP 0 685 556 to *Ghazarian et al.*

Rejection Under 35 U.S.C. § 112, First Paragraph

The outstanding Office Action includes a rejection under 35 U.S.C. § 112, first paragraph. This rejection is traversed.

The outstanding Office Action states:

“Insertion of the limitation directed to the use of the entire concentration range 0.001 % to 1 % of sulfate-containing anionic surfactant in the semen extender composition with lecithin has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of the entire concentration range 0.001% to 1% of sulfate-containing anionic surfactant.”

See the outstanding Office Action at page 2. It is submitted that the outstanding Office Action erroneously refers to the range 0.001% to 1%. Claims 1 and 21 state a range of “about 0.0001 wt.% to about 1 wt.% of anionic surfactant.” The Examiner’s attention is directed to independent claims 1 and 21 and to the specification at page 6, lines 20-31. Furthermore, the use of sodium lauryl sulfate is identified in a range of 0.01 wt.% to 1 wt.% in the specification at page 12, line 17. Clearly, the range identified in the specification at page 6, lines 20-31, is a generic range applicable to all the surfactants identified in the specification at page 6, lines 4-19, and the range disclosed in the specification at page 12, line 17, is an exemplary range for a specific component (e.g., sodium lauryl sulfate which is an example of an anionic surfactant).

The outstanding Office Action states:

“The generic disclosure of the as-filed specification (page 6) describes a variety of surfactants including anionic, cationic, nonionic, etc. (page 6) with nonionic

surfactant including glycerol esters and Tween 80 as preferred for the semen extender compositions."

See the outstanding Office Action at page 2. This statement in the outstanding Office Action is not entirely correct. The specification at page 6, lines 4-19, describes surfactants that can be used. In general, the surfactants that can be used are those surfactants that are characterized as sufficiently gentle so that they do not dissolve sperm cell membrane. Anionic surfactants such as sulfates (and in particular sodium lauryl sulfate and sodium laureth sulfate) are identified as exemplary surfactants. The specification further identifies sorbitan ester (a nonionic surfactant) as an exemplary surfactant. An exemplary sorbitan ester is stated to include polyoxyethylene sorbitan monooleate. The specification at page 6, lines 16-19, states that a "preferred polyoxyethylene sorbitan monooleate is available under the name Tween 80 from Sigma Chemical Company." This is not a statement that Tween 80 is the preferred surfactant or that nonionic surfactants are the preferred surfactants. Instead, this is simply a statement that Tween 80 is a preferred polyoxyethylene sorbitan monooleate. The statement in the outstanding Office Action that glycerol esters and Tween 80 are preferred for semen extender compositions is not a statement that can be reasonably inferred from a correct grammatical reading of the specification at page 6, lines 4-19.

The outstanding Office Action states that "the claimed concentration range 0.001% to 1% is linked to the use of nonionic surfactant as disclosed (page 6, lines 25-31)." See page 2 of the outstanding Office Action. This contention made in the outstanding Office Action is not current. Clearly, the specification describes many types of surfactants at page 6, lines 4-19. In fact, sulfates are identified as a type of anionic surfactant. See the specification at page 6, lines 12-13. The range "between about 0.0001 wt.% and about 1 wt.% surfactant" provided in the specification at page 6, lines 27-28, clearly is a generic reference to the surfactants identified in the specification at page 6, lines 4-19. The subsequent range of "between 0.001 wt.% and about 0.005 wt.%" is clearly an exemplary range for polyoxyethylene sorbitan monooleate. Thus, the interpretation in the outstanding Office Action that the range of 0.0001 wt.% to 1 wt.% surfactant is limited only to nonionic surfactants is clearly erroneous.

Finally, it is not understood why the outstanding Office Action refers to a range of "0.001% to 1%" when the claims do not identify that range. It is submitted that perhaps the Examiner has not read the actual range limitation with respect to the anionic surfactant.

In view of the above comments, the claimed invention is clearly supported by the specification and withdrawal of the rejection is requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31, and 33 stand rejected under 35 U.S.C. § 103(a) over European Patent No. EP 0 685 556 to *Ghazarian et al.*, U.S. Patent No. 3,444,039 to *Rajamannan*, U.S. Patent No. 6,130,034 to *Aitken*, U.S. Patent No. 6,140,121 to *Ellington et al.*, C. Helleman, and E. Giegoux, Deep Freezing of Rabbit Sperm, Effect of a Surfactant on Fertilizing Capacity, Zuchthyg., 23, 33-37 (1988)(*Hellemann et al.*) This rejection is traversed.

As discussed previously, *Ghazarian et al.* fail to disclose an aqueous ready to use semen extender composition comprising about 0.0001 wt.% to about 1 wt.% of anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention. It is submitted that the references relied upon in the outstanding Office Action would not have suggested modifying *Ghazarian et al.* to include an anionic surfactant comprising a sulfate according to the present invention.

Ghazarian et al. are directed to a vehicle for nonautonomous microorganisms of the animal kingdom to be kept alive outside their natural environment with a view to human interventions. The vehicle includes an aqueous medium comprising nutrition agents, buffers and mineral salts, and a protective product formed as a support for embryonic growth by a living organism, wherein the protective product is a lecithin extracted from soy seeds and introduced into the aqueous medium upon formation of the vehicle. See the English language translation of *Ghazarian et al.* on page 2, lines 1-17, and page 3, lines 20-27.

As discussed above, *Ghazarian et al.* fail to disclose a composition containing about 0.0001 wt.% to about 1 wt.% of anionic surfactant, comprising a sulfate, to reduce ice crystal formation during freezing of the composition. Furthermore, *Rajamannan*, *Aitken*, *Ellington et al.*, and *Hellemann et al.* would not have suggested modifying *Ghazarian et al.* to include about 0.0001 wt.% to about 1 wt.% of anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the presently claimed invention.

Rajamannan appears to be relied upon in the outstanding Office Action for the disclosure of buffering to a pH of 6 to 7.5 and for the disclosure of sodium citrate as a buffering agent. See *Rajamannan* at column 3, line 30 and lines 41-47. It is pointed out that *Rajamannan* is directed

at an egg yolk containing composition. See *Rajamannan* at column 1, lines 13-19, and the example disclosing the presence of egg yolk solids. Accordingly, *Rajamannan* is representative of prior art compositions that are based on the use of egg yolk. In contrast, the present invention is an improvement over prior art egg yolk-based compositions. Furthermore, *Rajamannan* fails to disclose or suggest the use of about 0.0001 wt.% to about 1 wt.% anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention.

It appears that the outstanding Office Action relies upon *Aitken* for the disclosure of an anti-oxidant. *Aitken* refers to an anti-oxidant such as vitamin E at column 1, line 50. It is pointed out, however, that *Aitken* is also directed at an egg yolk-containing system. See *Aitken* at column 1, lines 28-38. Clearly, *Aitken* is similarly representative of a prior art composition containing egg yolk. In contrast, the present invention is directed at a semen extender composition that is substantially free of animal products such as egg yolk. As discussed in the specification of the above-identified patent application beginning at page 3, line 23, it is believed that animal products, such as egg yolk, may contain nonpathogenic organisms or pathogenic organisms harmful to the host or cell provided in contact with the animal product. Accordingly, the present invention is directed at an improvement over those compositions that contain animal product. The outstanding Office Action fails to explain why one having ordinary skill in the art would look to a disclosure relating to the use of raw egg yolk for a suggestion to modify a composition that is free of raw egg yolk.

It is submitted that raw egg yolk contains a large number of various components and is a much more complicated system than the semen extender composition that does not contain raw egg yolk according to the present invention. Accordingly, the disclosure of the use of an anti-oxidant in a raw egg containing semen extender composition according to *Aitken* in no way suggests the use of an anti-oxidant in a non-raw egg containing semen extender composition.

Nevertheless, the outstanding Office Action fails to explain why one having ordinary skill in the art would have received a suggestion from *Aitken* to modify *Ghazarian et al.* to include about 0.0001 wt.% to about 1 wt.% anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention.

The outstanding Office Action appears to rely on *Ellington et al.* for the disclosure of various buffers such as EDTA and TRIS. See *Ellington et al.* at column 16, lines 52-63, and

column 19, line 28. The outstanding Office Action additionally refers to *Ellington et al.* for the disclosure of a balanced culture medium such as M199 at column 16, line 59, and contends that medium M199 suggests the use of polyoxyethylene sorbitan (Tween 80). It is submitted that Tween 80 is provided in medium M199 to help dissolve the other components in medium M199. There is no disclosure by *Ellington et al.* or ATCC Catalogue (Page 522) that Tween 80 can be useful for reducing ice crystal formation during freezing of a semen extender composition. One having ordinary skill in the art would not have received any suggestion from *Ellington et al.* or ATCC Catalogue (Page 522) that the incorporation of Tween 80 into the composition described by *Ghazarian et al.* would have any benefit for reducing ice crystal formation during freezing according to the present invention.

The reliance upon *Ellington et al.* and ATCC Catalogue (Page 522) is an example of the use of impermissible hindsight. There must be a suggestion to combine the references or make the modifications to achieve a *prima facie* case of obviousness. It is not enough to simply pick and choose various components from several references. The outstanding Office Action fails to explain why one having ordinary skill in the art would be motivated to select Tween 80 from the lengthy list of components identified in balanced culture M199, and then add that component to the composition described by *Ghazarian et al.* Nevertheless, it is pointed out that Tween 80 is an example of a nonionic surfactant. There is no suggestion by *Ellington et al.* that an anionic surfactant comprising a sulfate can be used to reduce ice crystal formation during freezing according to the present invention.

Hellemann et al. are apparently relied upon in the outstanding Office Action for the disclosure of sodium laurel sulfate in a composition intended for rabbit semen. See the abstract of *Hellemann et al.* Similar to *Rajamannan* and *Aitken*, *Hellemann et al.* are directed at compositions containing raw egg. Accordingly, *Hellemann et al.* are yet another example of a representative prior art composition that relies upon the use of raw egg yolk. In contrast, the present invention is directed at an improvement over those compositions that are based upon animal products such as raw egg yolk. The Examiner's attention is directed to the specification at, for example, page 3, line 8 through page 4, line 2. It is submitted that one having ordinary skill in the art would not have looked to *Hellemann et al.* for modifying a composition that does not contain raw egg yolk. Furthermore, the outstanding Office Action fails to provide a

sufficient reason to explain why one having ordinary skill in the art would modify *Ghazarian et al.* in view of the disclosure by *Hellemann et al.* to achieve the presently claimed invention.

The outstanding Office Action on page 6, merely states "the reference by *Hellemann et al.* teaches the use of surfactant sodium lauryl sulfate in the composition intended for animal semen preservation (see abstract)." However, *Hellemann et al.* fail to explain why one having ordinary skill in the art would be motivated to include sodium lauryl sulfate in a composition for freezing rabbit semen. Furthermore, one having ordinary skill in the art would not, from reading *Hellemann et al.*, understand why sodium lauryl sulfate would be included in a raw egg yolk-base composition, and would certainly not receive a suggest to include sodium lauryl sulfate in a semen extender composition that is substantially free of animal products. *Hellemann et al.* clearly provide no suggestion on how to modify a composition that is substantially free of raw egg yolk.

Finally, *Hellemann et al.* teach the use of an anionic surfactant to protect against damage caused by dimethyl sulfoxide (DMSO). See the first full paragraph of the translation of *Hellemann et al.* Accordingly, *Hellemann et al.* are concerned with the affect of sodium lauryl sulfate on a composition that utilizes DMSO. The results reported by *Hellemann et al.* are somewhat ambiguous but it appears that *Hellemann et al.* teach away from the use of sodium lauryl sulfate because it is detrimental except at high levels of DMSO where it is effective for increasing acrosomal activity. Accordingly, the general teachings of *Hellemann et al.* are to not use sodium lauryl sulfate unless there is a large presence of DMSO.

In contrast to *Hellemann et al.*, the present invention provides for the presence of a freeze agent comprising glycerol. The presently claimed invention does not require the presence of DMSO. In fact, because the claimed invention provides for the presence of glycerol, one would not include DMSO.

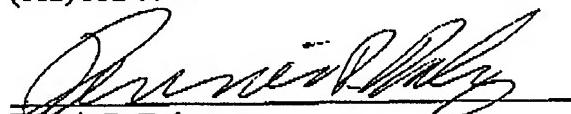
Clearly, one having ordinary skill in the art would not have received a suggestion from *Hellemann et al.* to modify *Ghazarian et al.* to include sodium lauryl sulfate. *Hellemann et al.* teach the use of sodium lauryl sulfate in response to a composition containing a relatively high level of DMSO in order to increase acrosomal integrity. Because the *Ghazarian et al.* do not include DMSO in their composition, it is submitted that one having ordinary skill in the art would not have received the suggestion from *Hellemann et al.* to modify *Ghazarian et al.* to include sodium lauryl sulfate.

In view of the comments, the presently claimed invention would not have been obvious from *Ghazarian et al.*, *Rajamannan, Aitken, Ellington et al.*, and *Hellemann et al.* Accordingly, withdrawal of this rejection is requested.

It is believed that this application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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